AFFIDAVIT OF SPECIAL AGENT VIVIAN M. BARRIOS <u>IN SUPPORT OF CRIMINAL COMPLAINT</u>

I, Special Agent Vivian M. Barrios, being duly sworn state:

INTRODUCTION

- 1. I have been a Special Agent for the Federal Bureau of Investigation ("FBI") since 2014 and am currently assigned to the Economic Crimes squad in Boston, Massachusetts. I received my Bachelor of Arts from the University of Colorado in 2002 and my Juris Doctorate from the University of Denver in 2005. In my current position as a Special Agent, I investigate white-collar crime, including money laundering, mail fraud, wire fraud, and bank fraud, among other things. I also have experience investigating telemarketing fraud, health care fraud, and violations of the Food, Drug, and Cosmetic Act (FDCA). Through my work, I am familiar with the use of computer and smartphone-based communication applications such as WhatsApp and Skype in furtherance of various crimes.
- 2. I submit this affidavit to establish probable cause in support of an application for a criminal complaint charging Manish KUMAR (KUMAR) with three crimes: first, false statements to federal officers, in violation of 18 U.S.C. § 1001(a)(2); second, conspiracy to distribute Schedule II and Schedule IV controlled substances, in violation of 21 U.S.C. §§ 846 and 841; and third, conspiracy to smuggle misbranded prescription drugs, including controlled substances, into the United States from Asia, in violation of 18 U.S.C. §§ 371 and 545 and 21 U.S.C. § 331(a).
- 3. The facts in this affidavit come from my personal involvement in this investigation, my training and experience, other law enforcement agents, KUMAR, documents and materials seized from KUMAR, the statements of co-conspirators, and other sources

identified below. This affidavit does not set forth all of my knowledge about this matter or investigation.

BACKGROUND

Prescription Drugs

- 4. The Food and Drug Administration (FDA) is the federal agency responsible for protecting the health and safety of the American public by enforcing the FDCA, 21 U.S.C. § 301, et seq. A main purpose of the FDCA is to ensure that human drugs sold in the United States are safe, effective, and bear labeling containing only true and accurate information. The FDA also regulates the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.
- 5. The FDCA defines "drug" to include "articles intended for use in the "diagnosis, cure, mitigation, treatment, or prevention of disease in man" and "articles (other than food) intended to affect the structure or any function of the body of man." 21 U.S.C. § 32l(g)(l)(B) and (C).
- 6. A "prescription drug" is any drug, which, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug," or any drug that is "limited by an approved application . . . to use under the professional supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(l).
- 7. Under the FDCA, "label" is defined as "a display of written, printed, or graphic matter upon the immediate container or any article." 21 U.S.C. § 32 l(k). The term "labeling" is

defined as "all labels and other written, printed, or graphic matter (1) upon any article of any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 32l(m).

8. Under the FDCA, it is illegal to introduce a "misbranded" drug into interstate commerce. A prescription drug is considered "misbranded" if dispensed and distributed without a valid prescription, 21 U.S.C. §353(b)(1), or if it is not approved for use in the United States by the FDA and its label does not contain adequate directions for safe use or was false or misleading in any particular manner, 21 U.S.C. §§ 352(a) and (f). Further, it is illegal for any entity other than a drug's manufacturer to import prescription drugs into the United States for sale to individuals in the United States. 21 U.S.C. §§ 331(t), 381(d)(1).

Controlled Substances

- 9. The Controlled Substances Act ("CSA") governs the manufacture, distribution, and dispensing of controlled substances in the United States. With limited exceptions for medical professionals, the CSA makes it unlawful for any person knowingly or intentionally to manufacture, to distribute, or to dispense a controlled substance or to conspire to do so.
- 10. The CSA and its implementing regulations set forth which drugs and other substances are defined by law as "controlled substances" and assigns those controlled substances to one of five schedules (Schedules I, II, III, IV, or V) depending on their potential for abuse, likelihood of physical or psychological dependency, accepted medical use, and accepted safety for use under medical supervision.
- 11. Under the CSA, it is illegal to distribute a Schedule II or a Schedule IV controlled substance to a patient unless the patient has a valid written prescription. 21 U.S.C. § 829.
- 12. Adderall, Tapentadol, tramadol, carisoprodol, modafinil, sildenafil, and tadalafil are prescription drugs within the meaning of 21 U.S.C. § 353(b)(l).

- 13. Adderall, which is a stimulant used to treat hyperactivity and narcolepsy, is a Schedule II controlled substance. 21 C.F.R. § 1308.12.
- 14. Tapentadol, which is a narcotic opioid marketed under the brand name, Nucynta, and under various off-brand or generic names, including TopCynta, is a Schedule II controlled substance. *Id*.
- 15. Tramadol, carisoprodol, and modafinil are Schedule IV controlled substances. 21 C.F.R. § 1308.14. Tramadol is a painkiller marketed overseas under a variety of generic names, including Oltram and Topdol. Carisoprodol is a sedative marketed under brand names such as Soma or Pain O' Soma. Modafinil is a stimulant marketed under a variety of names, such as Waklert and Modvigil.
- 16. Sildenafil, marketed in the United States as Viagra, and tadalafil, marketed in the United States as Cialis, are not controlled substances but do require a prescription. They are both used to treat erectile dysfunction.

The Defendant

- 17. KUMAR is an Indian national, who, before August 2019, resided in Dubai.

 KUMAR was a partner in Mihu Business Solutions Pvt Ltd. ("Mihu"), which among other commercial activities, operated as an internet pharmacy that sold generic prescription drugs to persons in the United States and shipped the drugs into the United States from India and Singapore, among other countries.
- 18. In August 2019, the FBI arrested KUMAR in the United States on charges including wire fraud, conspiracy to commit wire fraud, and aggravated identity theft, in violation of 18 U.S.C. §§ 1343, 1349, and 1028A, respectively. After KUMAR's arrest, KUMAR briefly cooperated with the government in hopes of receiving a reduced sentence in the pending case.

The government did not enter into a plea agreement with KUMAR. On November 5, 2020, without entering into a plea agreement, KUMAR pleaded guilty in Rhode Island to one count of wire fraud conspiracy, four counts of wire fraud, and two counts of aggravated identity theft.

See United States v. Kumar, No. 20-cr-00089-JJM-PAS (ECF Nos. 14 and 17) (D. R.I.). He was sentenced on February 11, 2021 to 24 months of incarceration and one year of supervised release.

PROBABLE CAUSE TO BELIEVE FEDERAL CRIMES WERE COMMITTED

False Statements

- 19. On or about February 27, 2020, as part of his purported cooperation with the government, KUMAR, accompanied by counsel, met with FBI agents and a federal prosecutor in Boston, Massachusetts. At the start of the meeting, and at least twice during the meeting by FBI agents, KUMAR was warned not to make false statements and told that making false statements could constitute a federal crime; following these warnings, KUMAR conferred privately with his counsel, who ultimately ended the interview after KUMAR made certain statements that the FBI questioned and challenged by presenting contradictory evidence.
- 20. During the meeting with the FBI agents and the federal prosecutor, KUMAR discussed Mihu's sales of generic erectile disfunction drugs manufactured in India to customers in the United States. However, KUMAR stated that his pharmaceutical business did not sell controlled substances, and made multiple statements that he was never part of any business deal in which any controlled substances were sold or shipped to a customer in the United States.
- 21. Based on information provided below, there is probable cause to believe that KUMAR knowingly and willfully made material false statements to the FBI when he stated that he had never been involved in the sale of controlled substances to persons in the United States.

Conspiracy to Distribute Controlled Substances and Prescription Drugs

- 22. Since KUMAR made his statements to the FBI agents on or about February 27, 2020, other FBI agents and I have reviewed hundreds of emails, instant messaging records, and numerous shipping and sales spreadsheets and invoices for KUMAR's pharmaceutical business from devices that the FBI seized from KUMAR at the time of his arrest and from e-mail accounts controlled and used by KUMAR.
- 23. Based on the FBI's review of documents and records seized from KUMAR, there is probable cause to believe that, beginning on a date unknown, but at least as early as in or about March 2015, and continuing until at least August 2019, KUMAR and persons known and unknown agreed with each other and operated together to sell and to ship Schedule II and Schedule IV controlled substances as well as India-produced generic prescription drugs to persons in Massachusetts and elsewhere in the United States.
- 24. The objects of the conspiracy were accomplished, in substance, by marketing drugs over the internet, radio, and telephone, employing call center operators in India to interact with consumers in the United States, obtaining credit card payments from those consumers, and having distributors in Asia ship the drugs into the United States.
- 25. Entity A was a company located in Mumbai, India, that shipped prescription drugs to the United States and to other countries for KUMAR and others. Entity A operated under at least four different names in its commercial transactions with KUMAR and his coconspirators. The FBI has reviewed hundreds of sales and shipment documents related to Entity A and has found no records of any prescriptions for any drugs shipped into the United States.
- 26. Spreadsheets obtained from KUMAR's devices and email accounts include records of payment, drugs shipped, and mail tracking numbers for shipments to persons in the

United States from drug distributors in Singapore and India, among other countries. The FBI has found no data pertaining to patient prescriptions for any drugs sold by KUMAR or his coconspirators. In addition, I have reviewed recordings of patients in the United States calling to place orders for shipments of drugs from KUMAR's company. None of the calls include information regarding prescriptions, and on at least one call, an agent for KUMAR's company stated that the company sold prescription drugs without prescriptions.¹

27. Since at least 2015, KUMAR's business involved sales of controlled substances. For example, one of KUMAR's devices contained a spreadsheet created on May 3, 2014, and last modified on December 18, 2015. The spreadsheet contains four individual sheets, entitled, respectively, "Sing Statement," "Fiji Statement," "DHL," and "Payment Details." "Sing Statement" contains orders primarily for tramadol, but also for carisoprodol, modafinil, and tapentadol, from March through December 2015. The sales records include shipment information for consumers in Massachusetts; for example, the sheet includes sale and shipment of 180 50mg tramadol pills to a consumer in Needham, Massachusetts on or about August 5, 2015 and October 5, 2015. "Fiji Statement" includes shipment records for tramadol and carisoprodol from March through October 2015. "DHL" includes tracking numbers for shipments of tramadol and carisoprodol to customers in numerous states. "Payment Details" includes a tally of payments by date. Based on my training and experience, I understand this business record to be evidence of a drug distribution scheme involving the shipment of controlled substances from Asia into the United States, starting by at least March 2015.

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¹The FBI has also interviewed persons in the United States who ordered prescription drugs, including controlled substances, from KUMAR and from his co-conspirators, and no customer interviewed by the FBI possessed a valid prescription for his or her purchases from KUMAR and his co-conspirators.

- 28. KUMAR's devices contained similar sales and shipment spreadsheets for 2016, 2017, and 2018. For example, a spreadsheet with a sheet called, "New Manish," included sales and shipping information for customers in May 2018, who bought various India-produced erectile dysfunction drugs and the Schedule IV drugs, tramadol, carisoprodol, and modafinil.
- 29. Another spreadsheet named, "17 aug ORDER," from KUMAR's devices includes six customers, including Consumer 1 in Massachusetts, who ordered tramadol in 100mg or 200 mg doses, with quantities ranging from 100 to 500 pills.
- 30. The FBI identified Consumer 1 based on his/her Massachusetts address and interviewed him/her. Consumer 1 told the FBI that he/she purchased tramadol on the internet and received tramadol in the mail, in brown envelopes from India and China. Consumer 1 showed agents a used package of tramadol pills and a pill bottle, and Consumer 1 said that he/she bought tramadol online because he/she could get more tramadol than a doctor would prescribe.
- 31. KUMAR personally performed numerous overt acts to further the conspiracies. For example, KUMAR struck a deal with CC-1, a person in business in the United States, to process sales of drugs using a merchant charge account. Their agreement, in a WhatsApp chat saved in a phone seized from KUMAR at the time of his arrest, explicitly described Schedule II "controlled" substances, as well as non-schedule prescription drugs ("regular stuff"):

Approximate Date	From	Message
1/15/2019	CC-1	How much controlled stuff can you sell?
1/15/2019	CC-1	What is your number 1 seller of controlled stuff
1/15/2019	KUMAR	4-5 orders start with
1/15/2019	CC-1	If we start selling you you must do more sales of regular stuff to help offset cost of controlled medicine
1/15/2019	KUMAR	Oxycodone Hydrocodone Xanax Adderall

1/15/2019	CC-1	This way I can take out cost of controlled stuff from your
		processing
1/15/2019	CC-1	Qty of each order 180 tablets?
1/15/2019	KUMAR	90%
1/15/2019	KUMAR	180 pills

- 32. KUMAR Account #1 is a Gmail account that KUMAR used from at least January 2018 until August 2019 to conduct and to arrange for sales and shipments of controlled substances and prescription drugs to persons in the United States. KUMAR's overt acts using Account #1 include the following:
 - a. On or about January 10, 2018, KUMAR used Account #1 to send CC-2, a person working for an overseas shipper, a spreadsheet ("Trama_&_Soma_Shipping.xls") of 32 orders for controlled substances and prescription drugs to be shipped to persons in the United States, including in Massachusetts. The orders included shipments for tapentadol (1 order); tramadol (25 orders); carisoprodol (1 order); and Viagra and Cialis (5 orders). The spreadsheet specifically identified one additional order for tramadol to be shipped only within the United States.
 - b. On or about April 16, 2018, KUMAR used Account #1 to send CC-2 a spreadsheet (Workbook1.xlxs) containing 9 orders for shipment of tramadol to consumers in 9 different states.
 - c. On or about June 21, 2018, CC-3, a person shipping drugs for KUMAR, sent

 Account #1 a spreadsheet (Invoice_Total.xlsx) referencing an account with

 \$112,952 "paid" and including 21 orders for prescription drugs sold to persons in
 the United States. The invoiced orders included 3 orders for the Schedule II
 controlled substance "Nucynta" (tapentadol).

- d. On or about February 13, 2019, KUMAR used Account #1 to make inquiries at a new shipper about the best price for tapentadol.
- e. On or about June 12, 2019, KUMAR used Account #1 to send CC-4, a person working for a shipper, 3 orders for shipments of tramadol to consumers in 3 states.
- 33. KUMAR Account #2 is a Microsoft email account that KUMAR used throughout the conspiracy to coordinate sales and shipment of prescription drugs to persons in the United States. KUMAR's overt acts using Account #2 include the following:
 - a. On or about March 30, 2016, KUMAR emailed CC-4, a person working for a shipper based in India, a spreadsheet (29th_shipping.xlsx) with a message stating, in relevant part, "Send hydro codone 5mg² last order I send yesterday if not then send 10 mg." The spreadsheet contained 23 orders to ship prescription erectile dysfunction drugs to persons in several states.
 - b. On or about July 28, 2017, KUMAR emailed CC-4 a spreadsheet
 (Shipping_File_For-27th_July_2017.xlsx) containing orders to ship prescription
 erectile dysfunction drugs to persons in several states, including Massachusetts.
 - c. On or about August 18, 2017, CC-5 forwarded to KUMAR at Account #2 a \$155 order for carisoprodol; along with the order, CC-4 gave KUMAR a recording of the sales call from the pharmaceutical representative to the customer in Michigan during which the customer confirmed a mailing address and chose a mailing

²Hydrocodone is a Schedule II controlled substance.

- method as well as confirmed payment method. The sales call did not include any information or inquiries regarding the customer's prescription for carisoprodol.
- d. On or about June 30, 2018, KUMAR used Account #2 to send Entity A an email instructing Entity A, "pls [sic] do the shipping," and reminding Entity A, "Two customer are pending to ship in MANISH2 file, TRAMADOL 100mg &50mg."
- 34. KUMAR's devices contain numerous spreadsheets containing records of sales of prescription drugs to persons in the United States, including in Massachusetts. For example, I have reviewed a spreadsheet forwarded to one of KUMAR's Microsoft email accounts on September 6, 2017, titled NEW MANISH ACCOUNT STATEMENT.xls. The spreadsheet shows that KUMAR sold 80 pills of "Suhagra-100" to a resident of Lynn, Massachusetts. I interviewed the purchaser, Consumer 2, who stated that he had ordered and subsequently received erectile dysfunction drugs several times over the last several years through a call center. Consumer 2 reported that he had asked the call center operator for the medication Viagra. Consumer 2 stated that he did not have a prescription from a doctor during the times he ordered the erectile dysfunction drugs and understood the pills were being shipped to him from overseas, potentially from India. Based on publicly available records and records stored in KUMAR's devices, Suhagra-100 is an Indian generic formulation of sildenafil, which is legally marketed in the United States as Viagra. Suhagra-100 is not approved by the FDA and is thus misbranded under the FDCA and may not be sold legally in the United States. I have personally reviewed hundreds of spreadsheets stored on KUMAR's devices that contain similar records of sales and shipment to persons in the United States of formulations of sildenafil and tadalafil that are not approved by the FDA.

35. KUMAR and his co-conspirators took steps to avoid detection and seizure of illegal pharmaceutical imports by United States customs, including by routing shipments through other countries. For example, in or about January 2016, after the "old Singapore shipping" went through Los Angeles where it "got stuck," Entity A began using a new shipping method that sent packages from Singapore to Switzerland and then into JFK International Airport in New York. Based on my experience and training and my knowledge of this case, I understand "stuck" to mean seized by United States Customs. For example, on about December 13, 2016, KUMAR asked Entity A to reship misbranded tadalafil to a customer in the United States because it was "stuck in custom[s]."

CONCLUSION

- 36. Based on the foregoing, there is probable cause to believe that KUMAR committed the following federal crimes:
 - a. False statement to federal officers, in violation of 18 U.S.C. § 1001(a)(2) on or about February 27, 2020;
 - b. Conspiracy to distribute illegally Schedule II drugs, including Tapentadol, Adderall, oxycontin, and hydrocodone, and Schedule IV drugs, including tramadol, carisoprodol, and modafinil, in violation of 21 U.S.C. § 846 and 841; and
 - c. Conspiracy to smuggle misbranded prescription drugs, including controlled substances, into the United States from Asia, in violation of 18 U.S.C. §§ 371 and 545 and 21 U.S.C. § 331(a).

/s/ Vivian M. Barrios

Vivian M. Barrios Special Agent Federal Bureau of Investigation Subscribed and sworn to by telephone in accordance with Federal Rule of Criminal Procedure 4.1 this ____day of May, 2021.

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Hon. M. Page Kelley

United States Magistrate Judge

District of Massachusetts